

**CAPNOMAC
ULTIMA™**

SERVICE MANUAL



Manual No. 878131-1

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Datex-Engstrom Division
Instrumentarium Corp.
P.O.Box 900 FIN-00031 Datex-Engstrom Finland
Tel. +358 9 39411 Fax +358 9 2787913
www.datex-engstrom.fi

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2 WARNINGS AND CAUTIONS

WARNINGS

A WARNING indicates that there is a possibility of injury to yourself or others.

PROPER GROUNDING: For protection against shock hazards, connect this monitor only to a three-wire, grounded, hospital grade receptacle. Do NOT remove the grounding prong from the power plug. Do NOT use extension cords or adapters of any type. The power cord and plug must be intact and undamaged. Should the power cord or plug become cracked, frayed, broken or otherwise damaged, it must be replaced. When connecting an external AC-operated equipment to the monitor, make sure that the equipment is properly grounded.

Do NOT perform any testing or maintenance on medical instruments while they are being used to monitor a patient.

Monitor models not including the automatic agent identification cannot distinguish between anaesthetic agents. Manufacturer assumes no liability for an incorrect anaesthetic selection.

When doing any work on the SpO₂ board care has to be taken that the patient isolation is not violated.

EXPLOSION HAZARD: Never use this monitor in the presence of flammable anaesthetics.

FUSE REPLACEMENT: For continued protection against fire hazard, replace only with the same type and rating of fuse.

Do not make any modifications to the patient cables without consulting the manufacturer.

ELECTRIC SHOCK HAZARDS:

The CRT display unit contains high voltage circuitry. In case of mechanical damage, carefully inspect the integrity of the patient isolation circuitry, CRT unit high voltage circuitry, the power supply transformer and primary wiring.

Do NOT immerse the monitor or probe in any liquid. An SpO₂ probe that is damaged or has been immersed may cause burns during electrosurgery.

Switch the power off and unplug the power cord before cleaning or service.

Do NOT touch any exposed wiring or conductive surface while the cover is off and the monitor is energized. The voltages present when the electric power is connected to the monitor can cause injury or death.

After doing any repair or calibration procedure to the monitor, perform a final electrical safety check and current leakage test.

The manufacturer accepts no responsibility for any modifications made to the monitor outside the factory.

CAUTIONS

A CAUTION indicates a condition that may lead to equipment damage or malfunction.

The tests and repairs described in this manual should only be done by trained personnel with proper tools and test equipment. Unauthorized service may void the monitor warranty.

Check the rear panel voltage setting before connecting the monitor to AC mains power outlet.

When the monitor is in use, leave space for ventilation to minimize heat accumulation inside the monitor.

Connect sample gas outlet on the monitor's rear panel to scavenging system to prevent room air pollution. Diameter of scavenging system tubing must be 2 to 3 times larger than that of sample out tubing to avoid changing the operating pressure of the monitor and consequent inaccurate readings or internal damage.

Diameter of calibration gas delivery tube must be 2 to 3 times larger than that of the sampling line to avoid overpressurization and consequent inaccurate calibration or internal damage of the monitor.

After performing any service always check the oxygen transducer by breathing into the sampling line and observing O₂ waveform display. After a moment's delay the wave should drop from the room air (21 %) to between 13 and 17 % O₂. The oxygen transducer uses room air as reference gas. It is possible for the transducer to malfunction or for the connecting tubing to be disconnected, and the digital display read 21 % O₂.

Before use, allow two minutes for warm-up and note any error messages or deviations from normal operation.

Always switch the monitor off before making any connections with external equipment.

Avoid ammonia-, phenol-, or acetone-based cleaners for they may damage the monitor's surface.

Electrostatic discharge through the pc boards may damage the components of the monitor. Handle all pc boards by their non-conductive edges and use anti-static containers when transporting them. Before replacing and repairing pc boards, wear a static control wrist strap to discharge any accumulated static charge.

Do not disassemble the ACX measuring unit. The unit is repaired and adjusted at the factory.

When removing or inserting any part into the monitor, be careful not to kink or damage the gas sample tubes. Leakages in the gas sampling system affect accuracy of measurement and are difficult to detect.

When servicing the sampling system, make sure not to leave any tubes touching the sampling pump. Abrasion may damage the tubes.

Do not apply tension to the power cord.

Do not autoclave the monitor nor probes.

Do not gas sterilize the monitor.

Equipment classification

Classification according to IEC 601-1:

* CLASS 1 equipment according to the type of protection against electrical shock.

* TYPE BF equipment according to the degree of protection against electrical shock.

* ORDINARY equipment according to the degree of protection against harmful ingress of water.

* Equipment not suitable for use in the presence of FLAMMABLE ANAESTHETIC MIXTURE with air or with OXYGEN/NITROUS OXIDE.

* CONTINUOUS OPERATION according to the mode of operation.

3 INTRODUCTION AND APPLICABILITY OF THIS MANUAL

3.1 Introduction and applicability of this manual

This service manual (Doc. No. 878131) and the Panasonic CRT Data Display Model M-K9101NB service manual (available from DATEX-ENGSTROM Division, order code 572760) provide information required to maintain and repair the CAPNOMAC ULTIMA™ ULT-1/ULT-S/ULT-V/ULT-SV/ULT-i/ULT-Si/ULT-Vi/ULT-SVi model monitors. This manual is applicable for the current production revision of the monitors. Differences between monitor revisions are summarized in Section 3.2 and the technical details of earlier revisions given in Chapter 11. Section 3.3 lists the technical (hardware) changes made to the monitor and Section 3.4 the software changes.

The revision of a monitor is changed when technical changes are made to the monitor resulting in new spare parts that are incompatible with earlier units. The last two digits of the monitor type designation denote the revision of the monitor (e.g. ULT-1-23-00 is a revision -00 unit).

Functional units of the monitor (pc boards) will have ID code stickers indicating the modification level of the production documentation. The code is shown as xxxxxx-y, where the "xx..." represents the part number and "y" the revision level, which is referred to when hardware changes are indicated in this manual.

The following list shows the models and their monitoring parameters.

| Model | Monitoring parameters |
|---------|---|
| ULT-1 | CO ₂ , N ₂ O, O ₂ , AA |
| ULT-S | CO ₂ , N ₂ O, O ₂ , AA, SpO ₂ |
| ULT-V | CO ₂ , N ₂ O, O ₂ , AA, Patient Spirometry™ |
| ULT-SV | CO ₂ , N ₂ O, O ₂ , AA, SpO ₂ , Patient Spirometry™ |
| ULT-i | CO ₂ , N ₂ O, O ₂ , AA, Agent ID |
| ULT-Si | CO ₂ , N ₂ O, O ₂ , AA, SpO ₂ , Agent ID |
| ULT-Vi | CO ₂ , N ₂ O, O ₂ , AA, Patient Spirometry™, Agent ID |
| ULT-SVi | CO ₂ , N ₂ O, O ₂ , AA, SpO ₂ , Patient Spirometry™, Agent ID |

The basic CAPNOMAC ULTIMA™ model ULT-1 measures CO₂, N₂O, O₂, and AA. The additional parameters and their symbols are explained below.

| | |
|---|---------------------|
| S | SpO ₂ |
| V | Patient Spirometry™ |
| i | Agent ID |

This manual describes all the functions offered by the CAPNOMAC ULTIMA™ monitor. Some of the functions may not be available in the monitor you are using.

ACX-200 Measuring board measures sevoflurane and desflurane in addition to halothane, isoflurane, and enflurane. The difference between the ACX-200 Measuring board and ACX-100 Measuring board is that the former contains several precision resistors. The ACX-200 Measuring board can simply be used to replace the ACX-100 Measuring board but not vice versa. Unless otherwise noted, the description of ACX-100 Measuring bench/board is also valid to ACX-200 Measuring bench/board.

ASX-100 identifies halothane, isoflurane, and enflurane. ASX-200 identifies halothane, isoflurane, enflurane, sevoflurane, and desflurane.

If ASX-100 is replaced by ASX-200 (or i-kit which includes ASX-200 is installed in the monitor), ACX must be upgraded to ACX-200 and the main software replaced (the i-kit includes the main software).

Please review the Operator's Manual to obtain a clear understanding of the monitor.

The manufacturer reserves the right to make changes in product specifications at any time and without prior notice. The information in this document is believed to be accurate and reliable; however the manufacturer assumes no responsibility for its use.

3.2 Summary of revision changes

Revision -00

Initial production revision of the monitor.

Revision -01 (except ULT-1/S-27-00)

Main differences to the revision -00 are:

The color of front panel, side and top covers, and bottom plate changed to white.

Revision -02 (except ULT-1/S-27-01 and ULT-V-xx-00)

Main differences to the revision -01 are:

ACX measuring board modified.

Software.

CPU board jumper X3 shorting pins 2 and 3 in order to use 2Mbit EPROM.

Revision -03 (except ULT-S/SV-25-00, ULT-1/S-27-02, ULT-V-xx-01, and ULT-i/Si/Vi/SVi-xx-00)

Main differences to the revision -02 are:

ACX-100 measuring unit is replaced by ACX-200 measuring unit.

Anaesthetic agent identification parameter (i) is added to Ultima.

Revision -04

Main differences to the revision -03 are:

ASX-100 identification unit is replaced by ASX-200.

Power supply board.

Software.

Revision -05 (-27 only)

Main differences to the revision -04 are:

- Improved EMC protection.

Revision -06

Current production revision of the monitor. Main differences to the revision -04/05 are:

- Improved EMC protection.
- CPU board (16 MHz High Speed CPU board installed).
- Improved SpO₂ Measuring board.
- Main software.

Additionally;

- PVX software and front mask for pediatric PVX measurement (all except -27 and -43).

NOTE: New main software and the High Speed CPU board are compatible with the old and new SpO₂ Measuring board, and with ASX-100, ASX-200, ACX-100, and ACX-200 sensors.

NOTE: New SpO₂ Measuring board operates only with the new main software and the High Speed CPU board.

Revision -07 (-27, -43)

- Software and front panel for paediatric PVX measurement are applied also to adaptations -27 and -43.
- In adaptation -27: new transformer case and new video display unit.
- Desflurane measurement is applied to adaptation -43.

Revision -07 (all except -27 and -43)

- CE mark
- new SpO₂ board, new oxygen sensor
- adaptations -21, -23, -25 replaced by -22

Revision -08 (-27 and -43)

- adaptation -43 CE mark
- adaptations -27 and -43 new SpO₂ board, new oxygen sensor

Revision -08 (all except -27 and -43), Revision -09 (-27, -43)

- new mains switch
- new rear panel
- main software
- video board (ASIC)

3.3 Manual updates

3.3.1 CAPNOMAC ULTIMA™ service manual changes

This is the update number 6 to the CAPNOMAC ULTIMA™ service manual. After this update, the manual covers 00 to 08 revision monitors, and revision 09 monitors of adaptations 27 and 43.

Manual update 6

Of all the pages taken out of this manual the following pages should be filed in chapter 11:

5-3, 5-4, 5-5, 5-31--5-34a, 5-36, 7-4

| Page | Change |
|--------------|--|
| Header page | new address and date |
| Section 1 | index revised |
| 3-4 | rev 07, 08 and 09 added |
| 3-5 | manual update page revised |
| 3-6 | update 6 added |
| 3-12, 3-13 | software changes for rev 07, 08 and 09 added |
| 4-13 | block diagram revised |
| 5-3 | gas sampling system diagrams revised |
| 5-4, 5-5 | gas sampling system layouts revised |
| 5-7 | ACX-100 replaced with ACX in general description |
| 5-13 | O2 field frequency changed from 165Hz to 110Hz |
| 5-23 | SpO2 board P/N changed |
| 5-29 | jumper x4 and x6 removed from CPU parts layout |
| 5-31, 32, 33 | video ASIC board information added |
| 5-35 | data retention voltage source changed from 15V to 5V |
| 5-36 | block diagram revised |
| 5-38a | adaptation 23 replaced by 22 |
| 6-4, 6-5 | information concerning N2O zero constant added |
| 6-15, 6-16 | troubleshooting table revised |
| 6-20 | troubleshooting instruction revised |
| 6-23 | troubleshooting table revised |
| 6-24 | instruction for ACX measuring chamber cleaning added |
| 7-1 | ASX-100 replaced by ASX in text |
| 7-4 | gas sampling system adjustment chart revised |
| 7-6 | O2 gain adjustment instruction changed |
| 7-10, 11 | Philips Video Display Unit schematics added |
| 8-2 | preoperative check list revised |
| 8-6 | preventive maintenance check list revised |
| 8-7...8-12 | preventive maintenance instructions added |
| 9-1, 2, 3, 4 | spare parts list revised |
| 9-6 | revision and main software history revised |
| 9-9 | text added to expl. picture of adaptation 27 |
| 9-10 | expl. picture of adaptation 27 rev 09 added |
| 12-9 | information concerning PBJ-124 printer added |

3.3.2 Record of manual updates carried out

| Update number | Carried out by Name | Date |
|---------------|---------------------|---------------------|
| 1 | Datex | May 2nd, 1991 |
| 2 | Datex | September 1st, 1992 |
| 3 | Datex | March 1st, 1993 |
| 4 | Datex | November 1st, 1993 |
| 5 | Datex | June 1st, 1994 |
| 6 | Datex-Engstrom | January 15th, 1997 |
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3.4 Software changes

The software code (six numbers) and revision number (if other than initial revision) are displayed on the screen during the startup sequence.

Software P/N 875345-4 is the initial production English language, 877340-2 is the initial production French language and 877412 is the initial production German language versions. These software are installed also in revision -01 monitors (see Section 9.1 for detail).

Software P/N 879016 is the revision -02 (except ULT-1/S-27-01 and ULT-V-xx-00) production English language, 879244 is the German language, and 879245 is the French language versions.

Differences to the initial software versions are:

30-minute trend added to Graphic trends of 2 h, 6 h, and 12 h.

Parameter configurations of the trend pages have been modified and a fourth page is added in order to include V-model parameters.

Numeric trend is added. Its time scale is 12 hours.

Selection of anaesthetic agent became easy. Pressing of the SET key is no longer necessary.

SEIKO DPU-411 printer is added to the printer selection.

Selection of O₂ scale is added in the SETUP SCREEN menu. The choices are 0 to 100 %, 10 to 60 %, DIFF/30 %, or DIFF/X % (X is the same number as in CO₂ scale selected, e.g., 6, 10, or 15). This selection is valid both in waveform and trends.

In the Start-up menu the user can now select to display either balance gas or MAC values. This selection also has an effect on graphic trends page 3.

Pleth amplitude indicating bar is now shown at the left corner of Pleth waveform field.

Display field of SpO₂ value digits can be moved from the lower right side (factory default) to the lower left side in Start-up menu.

EtCO₂ value digits can be enlarged as big as SpO₂ digits in Start-up menu. Factory default is the normal small size.

A 1.2 % scale is added for the anaesthetic agents display.

Anaesthetic agent concentration is now displayed with two decimals when the concentration is below 1 %.

Count-down display for the silence alarm suspend and apnea have been added.

Audible alarm for apnea can now be silenced in Start-up menu (except in French version).

Audible alarms for O₂ and anaesthetic agent are now activated only when breathing is detected.

Cautionary high and low alarms for anaesthetic agent have been added. The adjustment can be made between 0.1 % and 15 %.

User preset alarm limits for anaesthetic agents are now adjusted in MAC values which will then automatically be applied in corresponding percentages when an anaesthetic agent is selected.

Number of beeps in different alarm situation has been modified.

Shadow traces is now displayed when the user goes to any of the menus and returns to the normal display, so that the user will not lose waveform information during the menu period. These shadow traces are available for CO₂, O₂, and anaesthetic agent slow sweep speed waveforms.

Both serial string and graphic output are now sent via SERIAL & ANALOG I/O connector. The output selection is made in Start-up menu. AUX connector for graphic output will not be used any more.

Software P/N 879016-2.1 is the revision -03 (except ULT-S/SV-25-00, ULT-1/S-27-02, ULT-V-xx-01, and ULT-i/Si/Vi/SVi-xx-00) production English language, 879244-1.0 is the German language, and 879245-1.1 is the French language versions.

Differences to the previous level software versions are (see the Operator's Manual for more information):

Sevoflurane is measured and displayed (ACX-200 measuring unit).

Anaesthetic agent is identified and displayed (ASX unit in Ultima models with i-parameter).

MAC value of Isoflurane is changed from 1.3 % to 1.15 %

Numeric trends are now printed in graphic printers.

A line of numeric data of pressures and volumes is printed every 30 minutes and whenever the MARK key is pressed beside the graphic printout in graphic printer.

Software P/N 882312-1.0 is the revision -04 production English language, 882313-1.0 is the German language, and 882314-1.0 is the French language versions.

Differences to the previous level software versions are (see the Operator's Manual for more information):

Desflurane is measured and displayed (ACX-200 measuring unit).

Sevoflurane and desflurane are identified and displayed (ASX-200 unit in Ultima models with i-parameter).

Mixture of two agents is identified, and inspiratory and expiratory values for both agents are displayed.

While agent mixture is present, both agents' ET- and Fi- values are shown in U01-serial data string.

Selection "ID or SEV/DES" in user configuration menu is deleted.

ASX service page changed:

Total concentration of agent and relative proportions of all agents are displayed. Amplitude of spectrum is depending on concentration.

ASX delay measurement is added in gas service page.

High alarm limits for anaesthetic agent are changed as follows:

| | |
|------------------------|------|
| Halothane, Isoflurane | 6 % |
| Enflurane, Sevoflurane | 8 % |
| Desflurane | 20 % |

ACX measuring board compatibility with ACX benches.

P/N 874773-x...Can be used with ACX-100 bench only

P/N 875736-x...Can be used with ACX-100 bench only

P/N 878738-x...Can be used with ACX-100 bench only

P/N 880270-x...Can be used with ACX-100 and ACX-200 benches.

Software P/N 882916-1.0 is the revision -06 production English language, 882917-1.0 is the German language, and 882918-1.0 is the French language version. Those softwares operate only in 16 MHz (High Speed) CPU board.

Main differences to the previous level software versions are (see the Operator's Manual for more information):

1. Possibility to measure pediatric airway pressure and volume with Pedi-Lite sensor and new PVX software (884013).
2. Flow calibration in PVX is no longer necessary.
3. Spirometry parameter selections are added to normal screen.
4. Error message "MEMORY CHIP FAILURE" is added to indicate flatness of internal battery in SRAM D4 on CPU board.

The production softwares for revision -06 and -07 monitors were:

P/N 882916-3.0 in English (revision -06, except for adaptation -27 revision -07), P/N 882917-3.0 in German (revision -06), P/N 884234-2.0 in French (revision -07 for adaptation 43), and P/N 884203-3.0 in French (revision -06 for adaptation 29).

Changes made:

- PVX-measurement is improved
- Paediatric PVX-measurement and desflurane measurement are added to the French software

The production softwares for revision -06, -07 and -08 monitors were:

882916-3.1 in English (revision -07 except for adaptation -27 revision -08)
882917-3.1 in German (revision -07)
884203-2.0 in French (adaptation -43 revision -08, adaptation -29 revision -07)

Changes made:

- a bug in -3.0 fixed (missing 'SELECT AGENT' message in models without agent identification)
- 884203-2.0 for all french spoken countries since Sevoflurane and Desflurane were accepted also in France.

The current production softwares for revision -08 and -09 monitors are:

882916-4.0 in English (revision -08 except for adaptation -27 revision -09)

882917-4.0 in German (revision -08)

884203-4.0 in French (adaptation -29 revision -08, adaptation -43 revision -09)

889859-4.0 for model ULT-1A only. English revision -09.

890662-4.0 in Spanish (adaptation -40 revision -08)

Changes made:

- MAC value for Sevoflurane changed to 2.05%
- IBM-PRO added to the printer selection list
- Changes in Patient Spirometry recall function
- Text references "Datex" changed to "Datex-Engstrom"
- Time-out for ASX calibration extended from 15 seconds to 30 seconds
- Synchronization of the gas curves improved

4 GENERAL DESCRIPTION

4.1 Operational specifications

Automatic compensation for atmospheric pressure variation, CO₂/N₂O and CO₂/O₂ collision broadening effects

Gas Sampling Flow Rate: 200 ± 20 ml/min

Warm-up Time: 3 min to operation, 30 min for full specifications

| | | |
|-----------------------|---|---|
| CO₂ | Measuring Range: 0 to 10 % (0 to 76 mmHg, 0 to 10 kPa) Extended range: 10 to 15 % (76 to 114 mmHg, 10 to 15 kPa) (unspecified) Rise Time: ≤360 ms Gain Drift: ≤0.2 vol %/24h (0 to 8 %) ≤0.4 vol %/24h (8 to 10 %) Gain Temperature Drift: ≤0.2 vol %/10°C (0 to 8 %) ≤0.4 vol %/10°C (8 to 10 %) Nonlinearity: ≤0.2 vol % (0 to 8 %) ≤0.4 vol % (8 to 10 %) Display: Numeric Waveform | End tidal and inspired CO₂ Continuous, Scale 0 to 6, 0 to 10, or 0 to 15 % (0 to 6, 0 to 10, 0 to 15 kPa 0 to 50, 0 to 80, 0 to 110 mmHg) Sweep speeds 7 mm/s and 0.7 mm/s (15 and 150 seconds/full screen sweep) |
|-----------------------|---|---|

| | | |
|----------------------|---|--|
| O₂ | Measuring Range: 0 to 100% Rise Time: ≤480 ms Gain Drift: ≤2 vol %/24 h Gain Temperature Drift: ≤3 vol %/10°C Nonlinearity: ≤2 vol % Display: Numeric Waveform | End tidal and inspired O₂ Continuous, difference waveform scale is same as in CO ₂ waveform, Sweep speeds 7 mm/s and 0.7 mm/s. |
|----------------------|---|--|

| | | |
|-----------------------|-------------------------|------------------------|
| N₂O | Measuring Range: | 0 to 100 % |
| | Rise Time: | ≤360 ms |
| | Gain Drift: | ≤2 vol %/24 h |
| | Gain Temperature Drift: | ≤3 vol %/10°C |
| | Nonlinearity: | ≤2 vol % |
| | Display: | End tidal and inspired |

Anaesthetic Agent (performance with pure agents)

| | | Measuring Range | Accuracy |
|-------------------------|----------|---|-------------------------|
| HAL, ISO, ENF | | 0 to 5 % | ≤0.2 vol % |
| | Extended | 5 to 15 % | unspecified |
| SEV | | 0 to 8 % | ≤0.2 vol % |
| | Extended | 8 to 15 % | unspecified |
| DES | | 0 to 18 % | (0 to 5 %) ≤0.2 vol % |
| | | | (5 to 10 %) ≤0.5 vol % |
| | | | (10 to 18 %) ≤1.0 vol % |
| | Extended | 18 to 30 % | unspecified |
| Rise Time: | | ≤520 ms | |
| Gain Drift: | | ≤0.4 vol %/24 h | |
| Gain Temperature Drift: | | ≤0.4 vol %/10°C | |
| Display: | | | |
| Numeric | | End tidal and inspired | |
| Waveform | | Scale 0 to 1.2 %, 0 to 2.5 %, 0 to 5 %, 0 to 10 %, 0 to 20 %, Sweep speeds 7 mm/s and 0.7 mm/s. | |

Agent identification

| | |
|-----------------------------|--|
| Identified agents: | HAL, ENF, ISO, DES, SEV |
| Identification threshold*): | 0.15 vol % |
| Identification time*): | 30 seconds |
| Mixture warning: | Typically minor component concentration >0.3 vol % and >15% of total agent concentration |

*) Typical performance with pure agents

Airway Pressure (Paw)**

Accuracy: ± 1.5 cmH₂O
Resolution: 1 cmH₂O
Measuring Range: -20 to +80 cmH₂O
Extended Range: -99 to +99 cmH₂O (unspecified)

Flow**

Measuring Range (Adult): 1.5 to 100 l/min for both directions
(Pediatric): 0.25 to 25 l/min -"-
Display: Waveform
Two sweep speeds
Flow-volume loop

Tidal Volume (TV)**

Accuracy: (Adult) ± 6 % or 30 ml
(Pediatric) ± 6 % or 4 ml
Resolution: 1 ml
Measuring range: (Adult) 150 to 2000 ml
(Pediatric) 15 to 300 ml

Minute Volume (MV)**

Resolution: 0.1 l
Measuring range: (Adult) 2 to 15 l/min
(Pediatric) 0.5 to 5 l/min

**Values applicable if: Respiration rate is 4 to 50 breaths/min
I:E ratio is 1:3 - 1:05
Inner diameter of ET tube is ≥ 5.5 mm (adult) or 3 to 6mm (pediatric)

Respiratory Rate

Measuring Range: 4 to 60 breaths/min
Breath Detection: 1 % (7.6 mmHg) change in CO₂ level
Display Update Rate: breath-by-breath

Saturation (SpO₂)

Measuring Range: 40 to 100 %
Accuracy (SD): 100 to 80 % \pm 2 %
80 to 50 % \pm 3 %
50 to 0 % unspecified
Resolution: 1 digit (=1 %)

1 SD = 68 % of all readings in stable conditions.

The pulse oximeter accuracy measurements are statistically derived and correlated to simultaneous SaO₂ measured on an Instrumentation Laboratory IL/282 CO-oximeter

Display Averaging Time: 10 seconds, 5 seconds,
or beat-to-beat

Pulse Rate Measuring Range: 30 to 250 beats/min
Accuracy: 30 to 100 \pm 5 %
100 to 250 \pm 5 beats/min
Resolution: \pm 1 digit (1 bpm)
Display Averaging Time: 10 seconds,
Updated every 5 seconds

Plethysmographic Pulse Wave

Scale (gain) auto-set during start-up
Adjustable scale: 2, 5, 10, 20, 50

| | | |
|--------|-----------------|--|
| Alarms | Adjustable: | ETCO ₂ (high and low) FiO ₂ (high and low) Anaesthetic agent (high and low) Respiratory rate (high and low) CO ₂ rebreathing SpO ₂ (high and low) Pulse rate (high and low) Peak airway pressure (high and low) PEEP (high) Expiratory minute volume (high and low) |
| | Non-adjustable: | FiN ₂ O \geq 82 % FiO ₂ \leq 18 % Apnea Anaesthetic agent detected although not selected for display Occlusion Air leak Pulse search No probe Probe off Leak Disconnection Obstruction |

4.2 Technical specifications

| | |
|-------------------|---|
| Size (D x W x H): | 34 x 33 x 21.2 cm (excluding feet) (13.6 x 13.2 x 8.3 in) |
| Weight: | 12.5 kg (27.6 lb) |
| Display: | 9 inch monochrome video |
| Water Trap: | D-FEND™, operation based on the hydrophobic membrane, volume of the container 9 cm ³ . |

Electrical requirements

| | |
|--------------------|---|
| Voltage: | 100/115/220-240 V |
| Stability: | ±10 % of nominal voltage |
| Frequency: | 50-60 Hz |
| Power consumption: | 100 VA |
| Grounding: | Hospital grade |
| Interruptibility: | Data memory and alarm settings are saved during power failures up to 15 minutes |

Environmental requirements

| | |
|--------------------------|---|
| Space: | 50 x 50 x 30 cm (19 x 19 x 12 in) |
| Temperature (operation): | +10 to +35°C (50 to 95°F) |
| (storage): | -5 to +50°C (23 to 122°F) |
| Atmospheric pressure: | 500 to 800 mmHg (660 to 1060 mbar) |
| Humidity: | 10 to 90 % non-condensing (in airway 10 to 100 % condensing) |

| | |
|----------------------|---|
| Standards fulfilled: | IEC 601-1, Safety Class I, Type BF CSA C22.2, No. 125-M1984 |
|----------------------|---|

4.3 Equipment classification

Classification according to IEC 601-1:

- * CLASS 1 equipment according to the type of protection against electrical shock.

- * TYPE BF equipment according to the degree of protection against electrical shock is specified in the specifications of each parameter module.

- * ORDINARY equipment according to the degree of protection against harmful ingress of water.

- * Equipment not suitable for use in the presence of FLAMMABLE ANAESTHETIC MIXTURE with air or with OXYGEN/NITROUS OXIDE.

- * CONTINUOUS OPERATION according to the mode of operation.

4.4 Principle of operation

4.4.1 Principle of CO₂/N₂O/AA measurement

The CO₂, N₂O, and anaesthetic agent gas measurements are based on absorption of infrared light as it passes through the gas sample in measuring chamber in the photometer. The light absorption is measured at three wavelengths using an infrared detector. One of the wavelengths is that of the CO₂ absorption peak at 4.3 micrometers, the second is that of the N₂O absorption peak at 3.9 micrometers, and the third is that of the anaesthetic agent absorption peak at 3.3 micrometers. The signal processing electronics receive the signals from the IR detector and demodulate it to get DC components out of these signals which correspond to the content of each gas in the sample.

Figure 4.1 shows the CO₂/N₂O/AA gas absorption spectra.

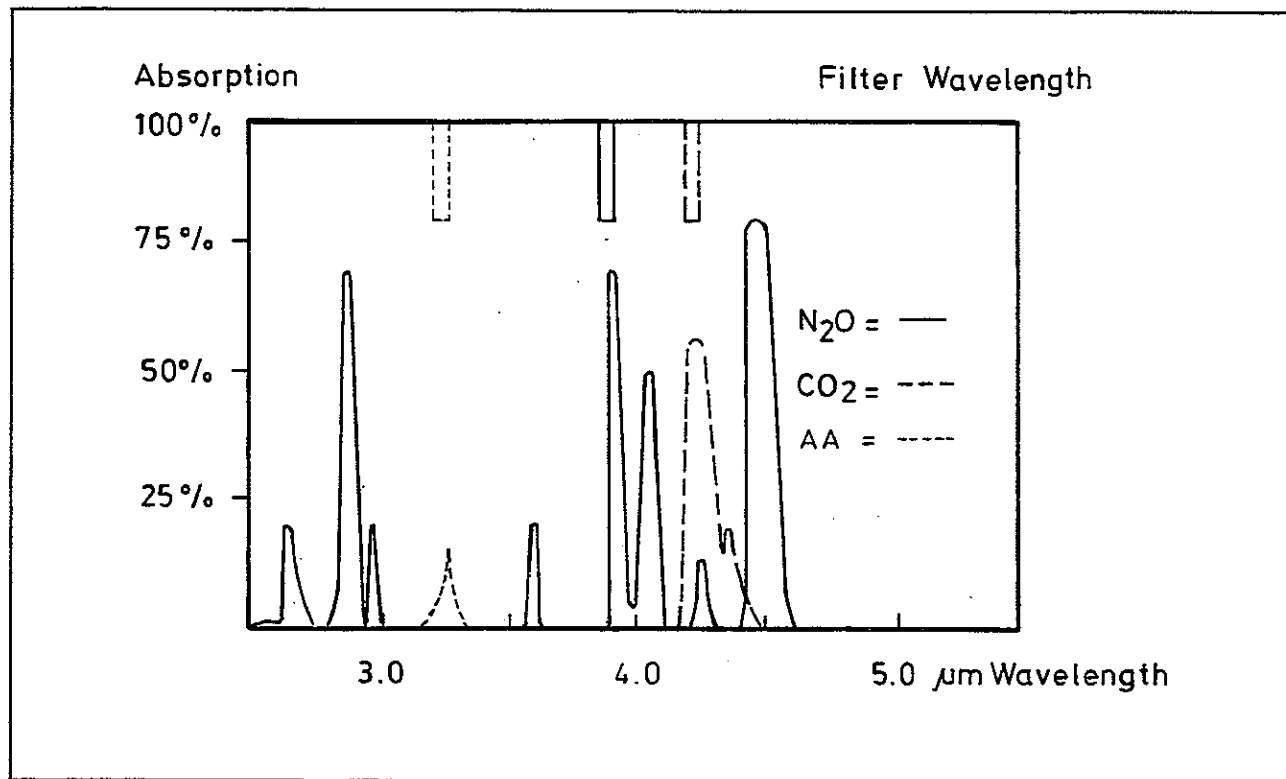


Figure 4.1 CO₂/N₂O/AA gas absorption spectra

4.4.2 Principle of O₂ measurement

The differential oxygen measuring unit uses the paramagnetic principle in a pneumatic bridge configuration. The signal picked up with a differential pressure transducer is generated in a measuring cell with a strong magnetic field that is switched on and off at a frequency of 110 Hz or 165 Hz. The output signal is a DC voltage proportional to the O₂ concentration difference between the two gases to be measured.

4.4.3 Principle of SpO₂ measurement

SpO₂

Oxygen is the most acutely necessary substrate for survival. A major concern during and after anesthesia is prevention of tissue hypoxia. Pulse Oximetry provides immediate and direct information on tissue oxygenation and, therefore, it is at present seen as a prerequisite of patient safety in anaesthesia departments.

Most of oxygen needed by the body is transported bound to hemoglobin. The total hemoglobin of blood is composed of oxygenated oxyhemoglobin (HbO₂), reduced or deoxygenated hemoglobin (Hb), and other forms of hemoglobin such as carboxyhemoglobin (HbCO) and methemoglobin (MetHb).

The absorption of light of normal human blood at different wavelengths is mainly determined by HbO₂ and Hb (see Figure 4.2). A Pulse Oximeter measures the relative absorption of light of blood at two wavelengths, one in the near infrared (about 900 nm) and the other in the red region (about 660 nm) of light spectrum. These wavelengths are emitted by LEDs in the SpO₂ probe, the light is transmitted through peripheral tissue and is finally detected by a PIN-diode opposite to LEDs in the probe. Pulse Oximeter derives the oxygen saturation SpO₂ using empirically determined relationship between the relative absorption at the two wavelengths and the arterial oxygen saturation SaO₂.

The total relative absorption of blood can be divided into components of tissue, venous blood, arterial blood, and the pulse added volume of arterial blood.

In order to focus the measurement on the arterial blood and thus to measure the arterial saturation accurately, Pulse Oximeters use the component of light absorption giving variations synchronous with heart beat as primary information on the arterial saturation. In fact, this invention was most essential for Pulse Oximetry and eventually made feasible the measurement of oxygen saturation noninvasively.

A general limitation of the above pulse oximetry principle is that due to only two wavelengths used only two hemoglobin species can be discriminated by the measurement.

The modern Pulse Oximeters are empirically calibrated either against fractional saturation SaO_{2frac},

$$\text{SaO}_{2\text{frac}} = \text{HbO}_2 / (\text{HbO}_2 + \text{Hb} + \text{Dyshemoglobin}),$$

or against functional saturation SaO_{2func},

$$SaO_{2func} = HbO_2 / (HbO_2 + Hb),$$

which is more insensitive to changes of carboxyhemoglobin and methemoglobin concentrations in blood.

The oxygen saturation percentage SpO_2 measured by Datex-Engstrom Monitor is calibrated against the functional saturation SaO_{2func} . The advantage of this method is that the accuracy of SpO_2 measurement relative to SaO_{2func} can be maintained even at rather high concentrations of carboxyhemoglobin in blood. Independent of the calibration method Pulse Oximetry is not able to correctly measure oxygen content of the arterial blood at elevated carboxyhemoglobin or methemoglobin levels, which clinically may be harmful for patient.

Plethysmographic pulse wave

The plethysmographic waveform is derived from the IR signal and reflects the blood pulsation at the measuring site. Thus the amplitude of the waveform represents the perfusion.

Pulse rate

The pulse rate calculation is done by peak detection of the plethysmographic pulse wave. The signals are filtered to reduce noise and checked to separate artifacts.

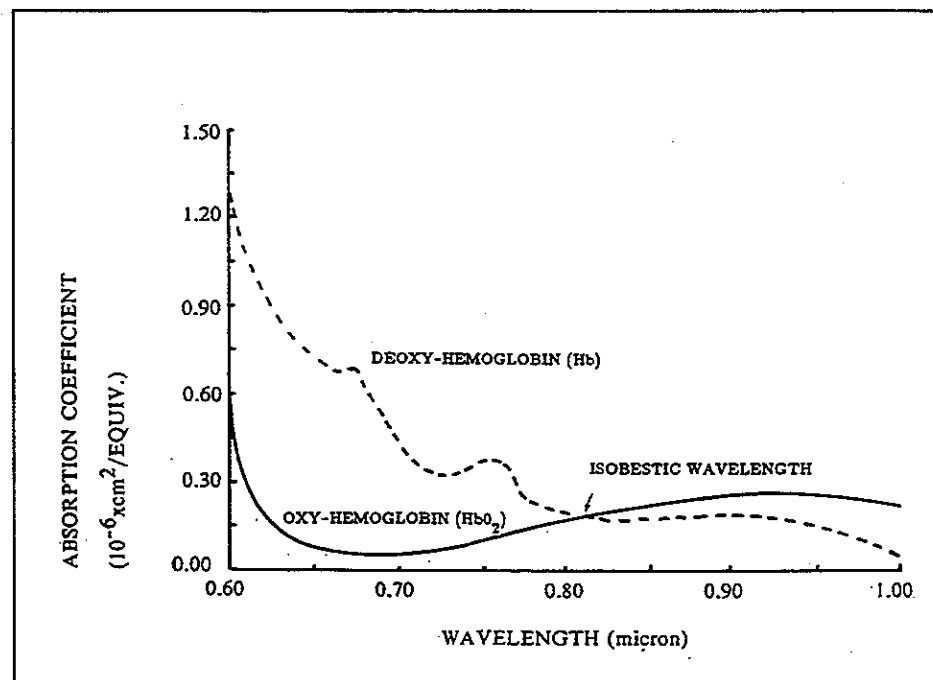


Figure 4.2 Absorption coefficients of oxy- and deoxy-hemoglobin in the red and near-infrared regions

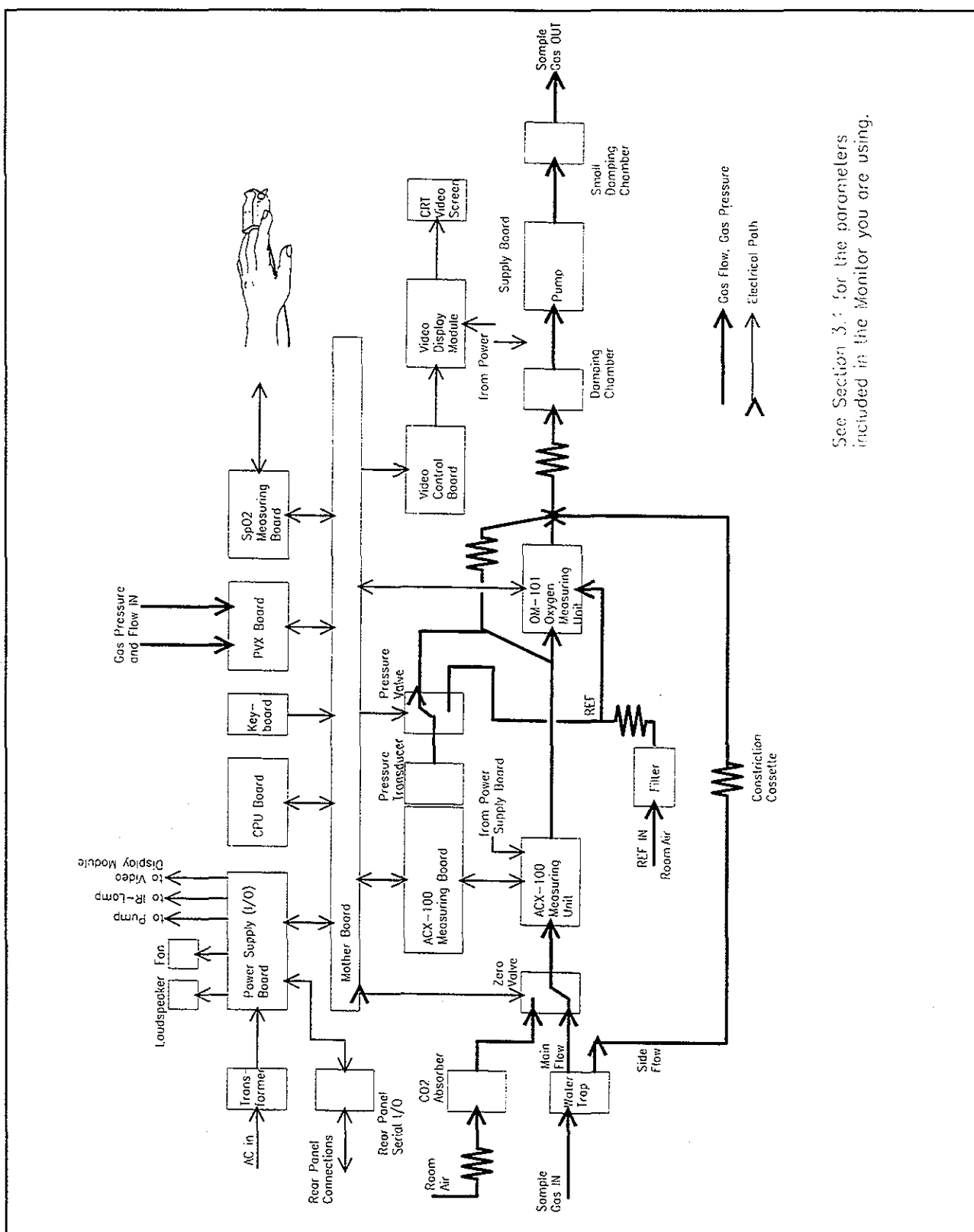
4.5 General block diagram

The monitor consists of the following modular parts (see page 3-1 for the parts included in the monitor you are using):

- The gas sampling system for CO₂/N₂O/O₂ Anaesthetic agent measurement
- ACX measuring unit
- ASX agent identification unit
- OM-101 oxygen measuring unit
- Measuring electronics
- PVX board for measuring airway volume and pressure
- Main CPU board including analog signal multiplexer, A/D converter, and real time clock
- Video control board to convert the CPU commands into video signal
- Video display module
- Transformer and power supply board to generate necessary voltages and I/O functions
- Mother board including signal buses and analog input signal buffers
- Tactile membrane keyboard
- Loudspeaker unit
- Probe and SpO₂/pulse oximeter measuring board

See Figure 4.3 for the monitor block diagram.

For monitor parts locations see the exploded view (Figure 9.1) in Chapter 9.



See Section 3.1 for the parameters included in the Monitor you are using.

Figure 4.3 General block diagram

4.6 Wiring diagram

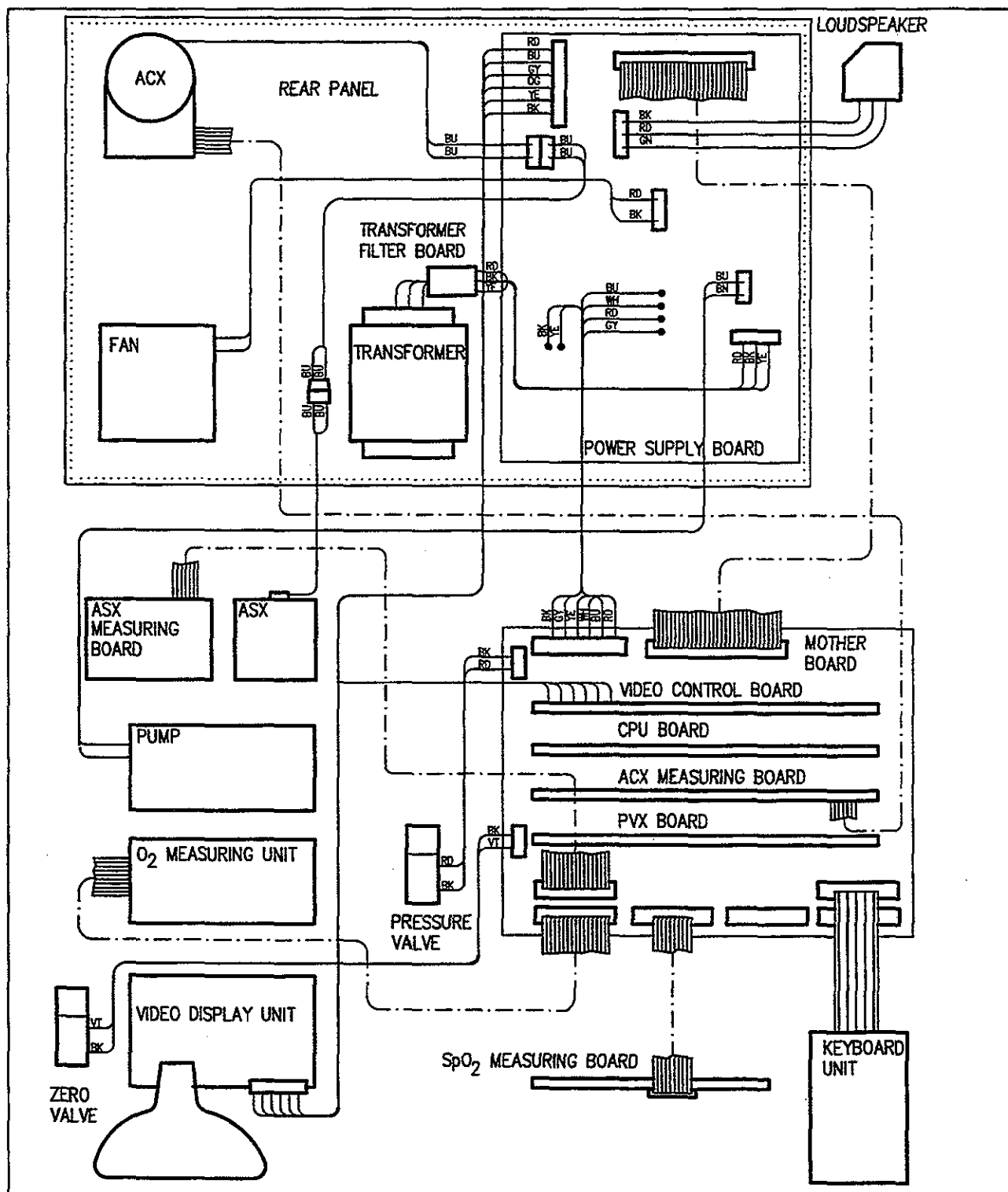


Figure 4.4 Wiring diagram

4.7 External connector configurations

4.7.1 Input/Output specifications

| Analog output | Scale | Output voltage |
|--------------------|-----------------------------|----------------|
| CO ₂ | 0 to 10 % | 0 to 10 V |
| O ₂ | 0 to 100 % | 0 to 10 V |
| N ₂ O | 0 to 100 % | 0 to 10 V |
| HAL, ENF, ISO, SEV | 0 to 10 % | 0 to 10 V |
| DES | 0 to 20 % | 0 to 10 V |
| SpO ₂ | 0 to 100 % | 0 to 10 V |
| Pleth wave | same as on screen | 0 to 10 V |
| Airway pressure | -20 to 0 cmH ₂ O | 0 to 2 V |
| | 0 to 80 cmH ₂ O | 2 to 10 V |
| Flow | -100 to 0 l/min | 0 to 5 V |
| | 0 to 100 l/min | 5 to 10 V |
| Volume | -2.5 to 0 l | 0 to 5 V |
| | 0 to 2.5 l | 5 to 10 V |

4.7.2 Connectors

Table 4.1 Pin order of the pulse oximeter probe connector

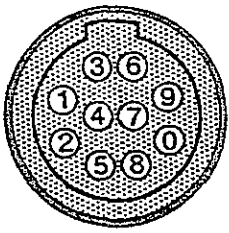
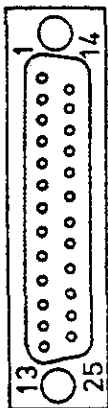
| | PIN | SIGNAL |
|--|-----|----------------------|
| Front view  | 1 | I _s |
| | 2 | I _b |
| | 3 | no connection |
| | 4 | Probe identification |
| | 5 | Probe identification |
| | 6 | Ground |
| | 7 | I _{led} |
| | 8 | VB(-) (+0.8 V) |
| | 9 | VB(+) +5 V |
| | 0 | Ground |

Table 4.2 Pin order of the SERIAL & ANALOG connector



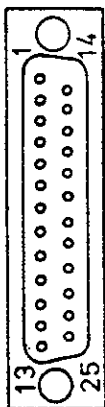
| PIN | SIGNAL | PIN | SIGNAL |
|-----|---------------|-----|--|
| 1 | Analog ground | 14 | O ₂ ¹⁾ 0-100 % |
| 2 | Serial out | 15 | +5 V |
| 3 | Serial in | 16 | N ₂ O ¹⁾ 0-100 % |
| 4 | RTS | 17 | Anaesthetic agent ¹⁾ 3) |
| 5 | CTS | 18 | v' or V |
| 6 | Gas freeze | 19 | SpO ₂ ¹⁾ 0-100 % |
| 7 | Signal ground | 20 | CO ₂ ¹⁾ 0-10 % |
| 8 | Test | 21 | +26 VDC out |
| 9 | +12 VDC | 22 | Pleth ¹⁾ 2) |
| 10 | -12 VDC | 23 | -26 VDC out |
| 11 | +15 VDC | 24 | 22 VAC |
| 12 | -15 VDC | 25 | 22 VAC |
| 13 | V or P | | |

1) 0 to 10 V

2) same scale as on screen

3) HAL, ENF, ISO, SEV: 0 to 10 %
DES 0 to 20 %

Table 4.3 Pin order of the AUX I/O connector



| PIN | SIGNAL | PIN | SIGNAL |
|-----|----------------|-----|---------------------------|
| 1 | Analog ground | 14 | Serial out(B) |
| 2 | Serial out (A) | 15 | +5 VDC |
| 3 | Serial in (A) | 16 | Serial in (B) |
| 4 | RTS (A) | 17 | PA5 |
| 5 | CTS (A) | 18 | PA6 |
| 6 | PB1 | 19 | RTS (B) |
| 7 | Signal ground | 20 | PA7, 5 V (Nurse call)* |
| 8 | PB0 | 21 | +26 VDC |
| 9 | +12 VDC | 22 | not in use |
| 10 | -12 VDC | 23 | -26 VDC |
| 11 | not in use | 24 | 22 VAC |
| 12 | not in use | 25 | 22 VAC |
| 13 | CTS (B) | | |

* max. 2 mA.

Video Connector Output

1 Vpp, 24 MHz, 75 Ohm, hsync 15.75 kHz, vsync 50 Hz

For internal connector pin configurations see Tables 5.3 to 5.23.

4.8 Principle of Patient Spirometry™

In anaesthesia, CMV (Controlled Mechanical Ventilation) is the mostly used ventilation mode. In this mode, mechanical breaths are delivered to the patient by a ventilator with a proper tidal volume (TV), respiration rate (RR), and inspiration/expiration ratio in time (I:E) determined by the settings of the ventilator.

Delivery of life support gases is based on pressure. However, without knowing volume measured of exhalation, one cannot be sure that a breath occurred. The ultimate goal of ventilation is to use the least amount of pressure to generate the most appropriate volume for each breath.

The Patient Spirometry™ monitors ventilation in anaesthesia. Both patient breathing circuit and the function of the ventilator are monitored. The following parameters are displayed:

Expiratory and inspiratory tidal volume (TV) in ml.

Expiratory and inspiratory minute volume (MV) in l/min.

Expiratory volume in first second (V1.0) in per cent.

Inspiration/expiration ratio in time (I:E)

Airway pressures: Peak pressure (P_{peak}), End inspiratory pressure (P_{plat}), Positive end expiratory pressure (PEEP), Real-time airway pressure waveform (P_{aw})

Flow: Real-time volume waveform (V')

Compliance (C)

Pressure volume loop

Flow volume loop

Airway pressure

PEEP, P_{peak} , and P_{plat} are measured by pressure transducer on the PVX board. Atmospheric pressure is used as a reference in measurement. The pressure measurement is made from the airway part that is closest to the patient between patient circuit and intubation tube.

Airway flow

The measurement is based on measuring the kinetic gas pressure and is performed using Pitot effect. Pressure transducer is used to measure the Pitot pressure. The obtained pressure signal is linearized and corrected according to the density of the gas. Speed of the flow is calculated from these pressure values and TV value is then integrated. MV value is further calculated and averaged using TV and RR (respiratory rate) values.

Real-time airway pressure and flow waveforms are displayed on the screen as shown in Figure 4.5.

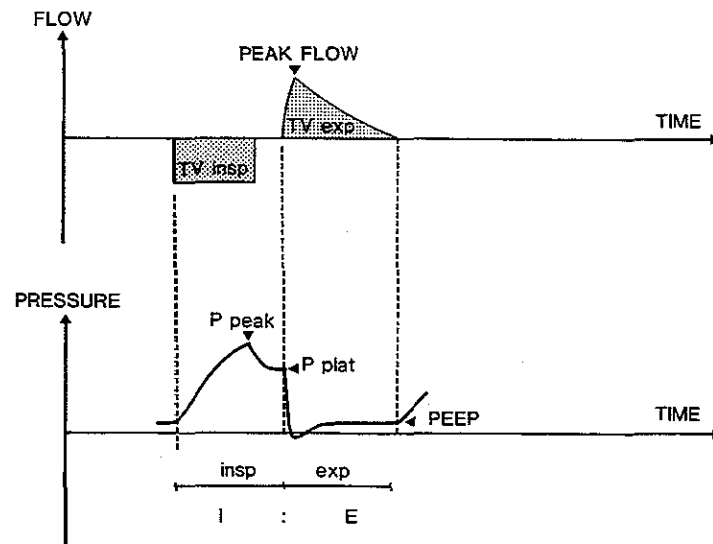


Figure 4.5 Example of Flow and Pressure Waveform

P_{peak} = Maximum pressure

P_{plat} = plateau pressure

PEEP = positive end expiratory pressure

V1.0 (V0.5 in Pedi mode)

During CMV, inspiration is an active phase done by a ventilator, while expiration is passive, caused by the elasticity of the chest wall, diaphragm and the lungs. Thus the expired volume during first second may change due to bronchial obstructions caused by lung diseases or mechanical obstacles.

Compliance

Compliance is the elasticity of the lungs and the chest wall. It is the subtotal of several parameters such as tidal volume, plateau pressure, and PEEP.

$$\text{Compliance} = \frac{\text{Expired tidal volume}}{\text{End inspiratory pressure} - \text{PEEP}}$$

The lower the compliance value is the more stiff the lungs are. Normal value for adults are 30 to 100 ml/cmH₂O.

Compliance is shown on the display in three different ways:

1. Actual digital value on the screen
2. In trend form
3. Angle of pressure-volume loop

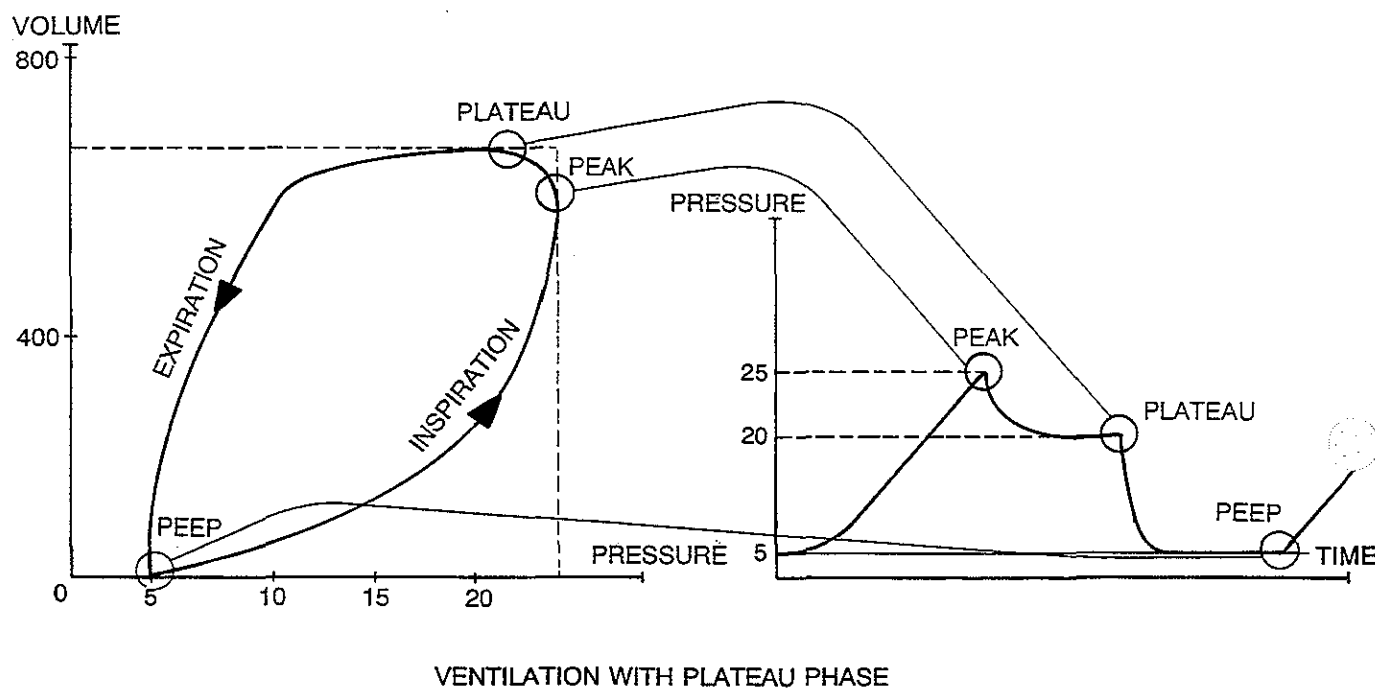


Figure 4.6 How to Find Corresponding Pressures From the Loop

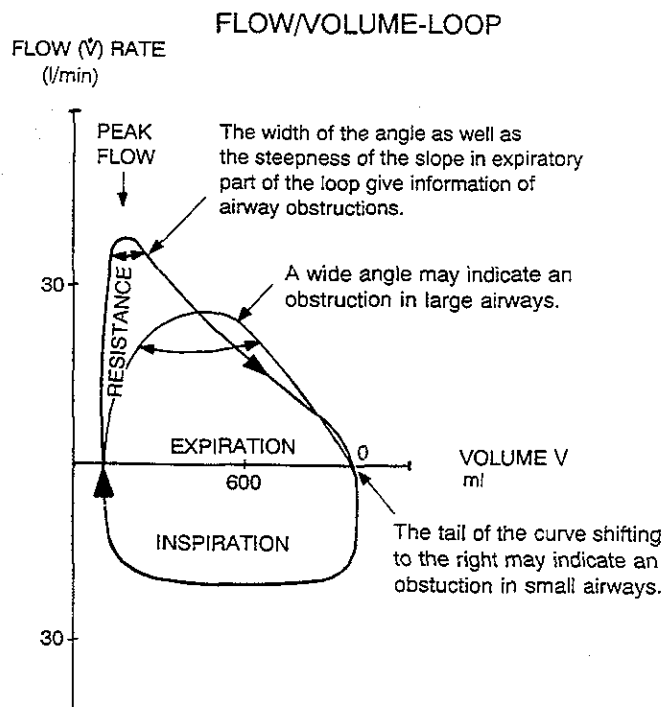
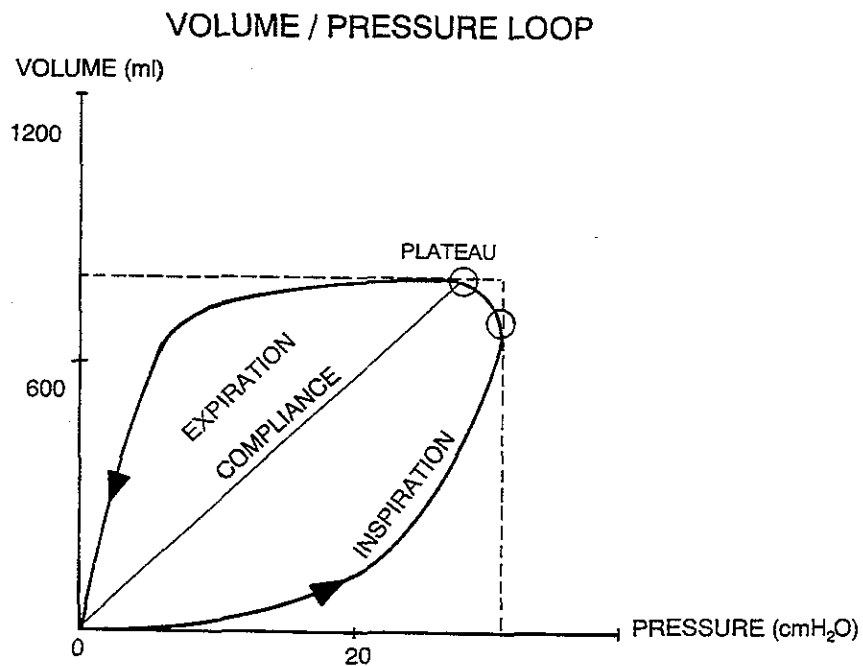


Figure 4.7 Pressure-volume loop, Flow-volume loop, and their interpretations

D-lite™ sensor

Two types of the D-lite™ sensors are available: disposable and reusable.

D-lite™ is designed to measure kinetic pressure by two-sided Pitot tube. The pressure reduction caused by measuring cross is taken into account, too, especially in small flows.

Velocity is calculated from pressure difference according to Bernoulli's law. Flow is then determined using the calculated velocity.

$$v = 2 \times dP / \quad (\text{Bernoulli's law})$$

$$F = v \times A$$

where,

| | |
|----|--|
| F | = flow (l/min) |
| v | = velocity (m/s) |
| A | = cross area (m ²) |
| dP | = pressure difference (cmH ₂ O) |
| | = density (kg/m ³) |

Finally the volume information is obtained by integrating the flow signal.

From revision 06 the monitors (except for adaptations -27 and -43 only from the revision -07 on) can measure paediatric spirometry with Pedi-lite™ sensor. This sensor is used for patients of 3 to 30 kg, and is available as a reusable sensor only.

4.9 Principle of Agent Identification

The anaesthetic agent identification bench identifies halothane, enflurane, isoflurane, desflurane and sevoflurane.

The operation of the bench is based on infrared absorption at 3.3 μm range. It measures the spectrum of the gas between 3.24 μm and 3.39 μm . Because the spectrum of each of the anaesthetic agents is different it is possible to identify them.

The bench consists of an infrared source, a measuring chamber, a rotating filter and a detector. The peak wavelength of the narrow bandpass filter changes when the angle between the light path and the filter is changed. When the filter rotates the required spectrum is scanned through.

The agent or a mixture of agents is calculated from the measured spectrum using stored reference spectrums of each agent.

Figure 4.8 shows the absorption spectra of anaesthetic agents.

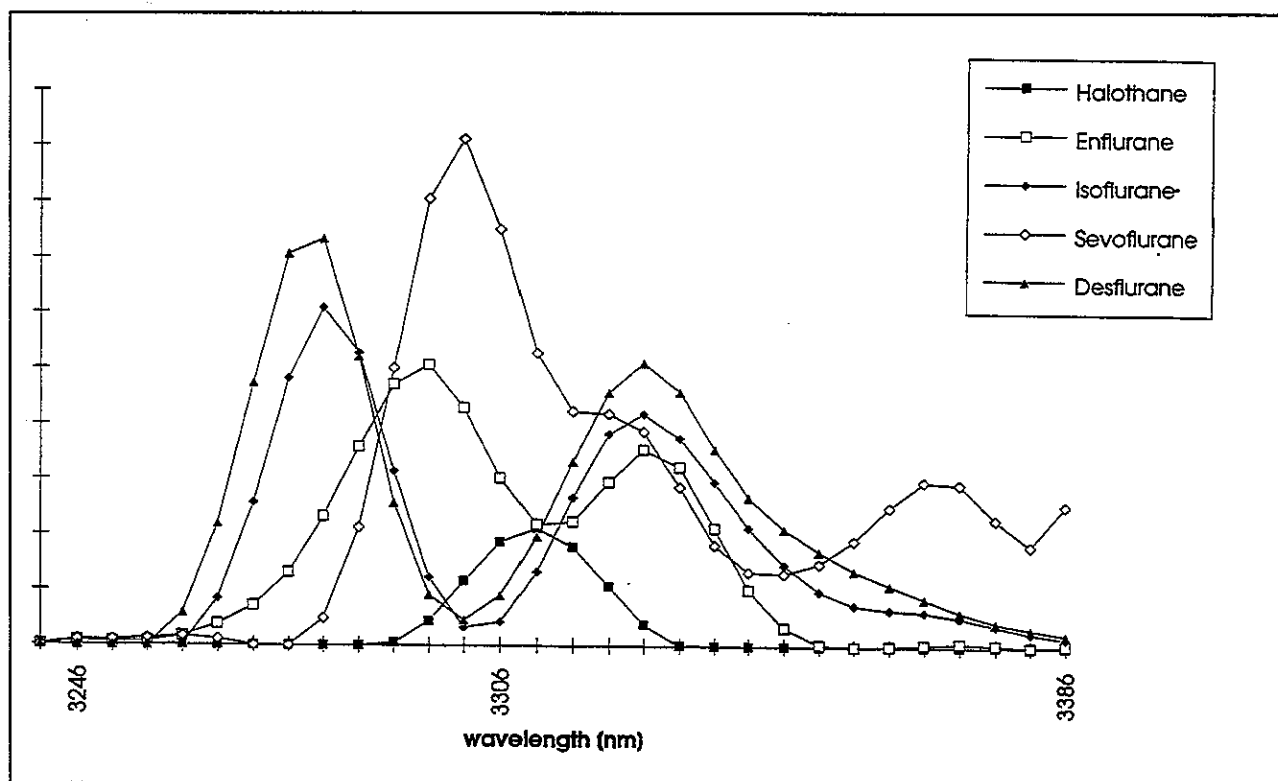


Figure 4.8 Anaesthetic Agents Gas Absorption Spectra

